



JAN 5 2000

Re: Therma Choice Uterine Ballon Therapy System 5,105®  
Docket No. 98E-0485

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 5,105,808 filed by Gynelab Products, Inc. under 35 U.S.C. § 156. The patent claims the medical device Therma Choice Uterine Ballon Therapy System 5,105®, premarket approval application PMA P970021.

In the May 28, 1999, issue of the Federal Register (64 Fed. Reg. 29046), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 24, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Talivaldis Cepuritis  
Olson & Hierl, Ltd.  
36th Floor  
20 North Wacker Drive  
Chicago, IL 60606